

AMENDED IN SENATE APRIL 27, 2009

AMENDED IN SENATE APRIL 16, 2009

AMENDED IN SENATE APRIL 14, 2009

SENATE BILL

No. 303

Introduced by Senator Alquist
(Coauthor: Senator Florez)

February 25, 2009

An act to amend Sections 1418.9 and 1599.1 of, *and* to add Section 1599.15 to, ~~and to repeal and add Section 1599.3 of,~~ the Health and Safety Code, relating to nursing facility residents.

LEGISLATIVE COUNSEL'S DIGEST

SB 303, as amended, Alquist. Nursing facility residents: informed consent.

Existing law provides that patients of skilled nursing facilities and intermediate care facilities have prescribed rights.

This bill would add to these rights the right of every resident to receive all information that is material to an individual's decision concerning whether to accept or refuse any proposed treatment or procedure. This bill would make the physician responsible for disclosing the material information to the resident and obtaining his or her informed consent.

This bill would require that informed consent, as defined, be obtained in accordance with the above requirements of the bill, with respect to a resident's decision to accept or reject the administration of a psychotherapeutic drug.

This bill would also require the State Department of Public Health to inspect for compliance with this requirement during prescribed inspections.

Existing law prescribes the persons to whom the rights of a resident of a skilled nursing or intermediate care facility devolve if the resident is judicially determined to be incompetent, or who is found by his or her physician to be medically incapable of understanding his or her rights or the nature and consequences of proposed treatment, or who exhibits a communication barrier.

~~This bill would repeal these provisions, and, instead, would provide that a resident's representative, as defined, shall have the rights of a resident of a skilled nursing or intermediate facility who lacks the capacity to understand his or her rights or the nature and consequences of proposed treatment. The resident's incapacity would be determined by a court in accordance with state law or by the resident's physician unless the physician's determination is disputed by the resident or the resident's representative.~~

Under existing law, the Long-Term Care, Health, Safety, and Security Act of 1973, an attending physician and surgeon that seeks to prescribe, order, or increase an order for an antipsychotic medication for a resident of a skilled nursing facility is required to obtain the informed consent of that resident. A violation of this provision is a misdemeanor.

This bill would apply the definition of "informed consent" contained in the bill to this provision. Because this bill would change the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. This act shall be known, and may be cited, as the
- 2 Nursing Facility Resident Informed Consent Protection Act of
- 3 2009.
- 4 SEC. 2. The Legislature finds and declares all of the following:
- 5 (a) The protection of residents in California's nursing facilities
- 6 is of paramount importance to the citizens of California.

1 (b) Almost 60 percent of California nursing facility residents
2 are prescribed psychoactive drugs, many of which have dangerous
3 side effects.

4 (c) Nearly 20 percent of California nursing facility residents are
5 receiving powerful antipsychotic drugs that are not intended or
6 approved for the resident's underlying medical condition.

7 (d) The United States Food and Drug Administration (FDA)
8 has issued black box warnings for the antipsychotic drugs most
9 commonly provided to nursing facility residents. The warnings
10 state that these antipsychotic drugs greatly increase the risk of
11 death for seniors with dementia.

12 (e) Nursing facility residents and resident's representatives
13 rarely see the medication inserts that provide the black box
14 warnings and often do not receive sufficient information about the
15 side effects of medications.

16 (f) Nursing facility residents and resident's representatives must
17 be well-informed in advance about the risks of proposed
18 antipsychotic drugs and their consent must be obtained before
19 medications are used.

20 (g) California's existing regulations on informed consent for
21 nursing facility residents are rarely enforced.

22 (h) It is, therefore, the intent of the Legislature to enact
23 legislation that would do all of the following:

24 (1) Codify provisions that establish a resident's right to informed
25 consent concerning the use of psychotherapeutic drugs.

26 (2) Specify that residents and their representatives must be
27 informed in writing about the content of black box warnings for
28 proposed drugs and whether the drug's proposed use has been
29 approved by the FDA.

30 (3) Require the State Department of Public Health to evaluate
31 nursing facility compliance with these provisions during periodic
32 state licensing inspections.

33 SEC. 3. Section 1418.9 of the Health and Safety Code is
34 amended to read:

35 1418.9. (a) If the attending physician and surgeon of a resident
36 in a skilled nursing facility prescribes, orders, or increases an order
37 for an antipsychotic medication for the resident, the physician and
38 surgeon shall do both of the following:

39 (1) Obtain the informed consent, in accordance with the
40 requirements of subdivision (j) of Section 1599.1 and Section

1 1599.15, of the resident for purposes of prescribing, ordering, or
2 increasing an order for the medication.

3 (2) Seek the consent of the resident to notify the resident's
4 interested family member, as designated in the medical record. If
5 the resident consents to the notice, the physician and surgeon shall
6 make reasonable attempts, either personally or through a designee,
7 to notify the interested family member, as designated in the medical
8 record, within 48 hours of the prescription, order, or increase of
9 an order.

10 (b) Notification of an interested family member is not required
11 under paragraph (2) of subdivision (a) if any of the following
12 circumstances exist:

13 (1) There is no interested family member designated in the
14 medical record.

15 (2) The resident has been diagnosed as terminally ill by his or
16 her physician and surgeon and is receiving hospice services from
17 a licensed, certified hospice agency in the facility.

18 (3) The resident has not consented to the notification.

19 (c) As used in this section, the following definitions shall apply:

20 (1) "Resident" means a patient of a skilled nursing facility who
21 has the capacity to consent to make decisions concerning his or
22 her health care, including medications.

23 (2) "Designee" means a person who has agreed with the
24 physician and surgeon to provide the notice required by this
25 section.

26 (3) "Antipsychotic medication" means a medication approved
27 by the United States Food and Drug Administration for the
28 treatment of psychosis.

29 (4) "Increase of an order" means an increase of the dosage of
30 the medication above the dosage range stated in a prior consent
31 from the resident.

32 (d) This section shall not be construed to require consent from
33 an interested family member for an attending physician and surgeon
34 of a resident to prescribe, order, or increase an order for
35 antipsychotic medication.

36 SEC. 4. Section 1599.1 of the Health and Safety Code is
37 amended to read:

38 1599.1. Written policies regarding the rights of patients shall
39 be established and shall be made available to the patient, to any
40 guardian, next of kin, sponsoring agency or representative payee,

1 and to the public. Those policies and procedures shall ensure that
2 each patient admitted to the facility has the following rights and
3 is notified of the following facility obligations, in addition to those
4 specified by regulation:

5 (a) The facility shall employ an adequate number of qualified
6 personnel to carry out all of the functions of the facility.

7 (b) Each patient shall show evidence of good personal hygiene
8 and be given care to prevent bedsores, and measures shall be used
9 to prevent and reduce incontinence for each patient.

10 (c) The facility shall provide food of the quality and quantity
11 to meet the patients' needs in accordance with physicians' orders.

12 (d) The facility shall provide an activity program staffed and
13 equipped to meet the needs and interests of each patient and to
14 encourage self-care and resumption of normal activities. Patients
15 shall be encouraged to participate in activities suited to their
16 individual needs.

17 (e) The facility shall be clean, sanitary, and in good repair at all
18 times.

19 (f) A nurses' call system shall be maintained in operating order
20 in all nursing units and provide visible and audible signal
21 communication between nursing personnel and patients. Extension
22 cords to each patient's bed shall be readily accessible to patients
23 at all times.

24 (g) (1) If a facility has a significant beneficial interest in an
25 ancillary health service provider or if a facility knows that an
26 ancillary health service provider has a significant beneficial interest
27 in the facility, as provided by subdivision (a) of Section 1323, or
28 if the facility has a significant beneficial interest in another facility,
29 as provided by subdivision (c) of Section 1323, the facility shall
30 disclose that interest in writing to the patient, or his or her
31 representative, and advise the patient, or his or her representative,
32 that the patient may choose to have another ancillary health service
33 provider, or facility, as the case may be, provide any supplies or
34 services ordered by a member of the medical staff of the facility.

35 (2) A facility is not required to make any disclosures required
36 by this subdivision to any patient, or his or her representative, if
37 the patient is enrolled in an organization or entity that provides or
38 arranges for the provision of health care services in exchange for
39 a prepaid capitation payment or premium.

1 (h) (1) If a resident of a long-term health care facility has been
2 hospitalized in an acute care hospital and asserts his or her rights
3 to readmission pursuant to bed hold provisions, or readmission
4 rights of either state or federal law, and the facility refuses to
5 readmit him or her, the resident may appeal the facility's refusal.

6 (2) The refusal of the facility as described in this subdivision
7 shall be treated as if it were an involuntary transfer under federal
8 law, and the rights and procedures that apply to appeals of transfers
9 and discharges of nursing facility residents shall apply to the
10 resident's appeal under this subdivision.

11 (3) If the resident appeals pursuant to this subdivision, and the
12 resident is eligible under the Medi-Cal program, the resident shall
13 remain in the hospital and the hospital may be reimbursed at the
14 administrative day rate, pending the final determination of the
15 hearing officer, unless the resident agrees to placement in another
16 facility.

17 (4) If the resident appeals pursuant to this subdivision, and the
18 resident is not eligible under the Medi-Cal program, the resident
19 shall remain in the hospital if other payment is available, pending
20 the final determination of the hearing officer, unless the resident
21 agrees to placement in another facility.

22 (5) If the resident is not eligible for participation in the Medi-Cal
23 program and has no other source of payment, the hearing and final
24 determination shall be made within 48 hours.

25 (i) Effective July 1, 2007, Sections 483.10, 483.12, 483.13, and
26 483.15 of Title 42 of the Code of Federal Regulations in effect on
27 July 1, 2006, shall apply to each skilled nursing facility and
28 intermediate care facility, regardless of a resident's payment source
29 or the Medi-Cal or Medicare certification status of the skilled
30 nursing facility or intermediate care facility in which the resident
31 resides, except that a noncertified facility is not obligated to provide
32 notice of Medicaid or Medicare benefits, covered services, or
33 eligibility procedures.

34 (j) The resident shall have the right to receive all information
35 that is material to an individual's decision concerning whether to
36 accept or refuse any proposed treatment or procedure. The
37 disclosure of material information for administration of
38 psychotherapeutic drugs shall include the disclosures required by
39 Section 1599.15.

1 SEC. 5. Section 1599.15 is added to the Health and Safety
2 Code, to read:

3 1599.15. (a) As used in this section, the following definitions
4 shall apply:

5 (1) “Attending physician” means the physician chosen by the
6 resident or the resident’s representative to be responsible for the
7 medical treatment of the resident in the facility.

8 (2) “Informed consent” means the voluntary agreement of a
9 patient or a resident’s representative to accept a treatment or
10 procedure after receiving information in accordance with
11 subdivisions (b) to (f), inclusive, and subdivision (j) of Section
12 1599.1.

13 (3) “Psychotherapeutic drug” means a medication to control
14 behavior or to treat thought disorder processes.

15 (b) It is the responsibility of the attending physician to determine
16 what information a reasonable person in the resident’s condition
17 and circumstances would consider material to a decision to accept
18 or refuse a proposed treatment or procedure. Information that is
19 commonly appreciated need not be disclosed. The disclosure of
20 the material information and obtaining informed consent shall be
21 the responsibility of the physician.

22 (c) The information material to a decision concerning the
23 administration of a psychotherapeutic drug shall include, but not
24 be limited to, the following:

25 (1) The reason for the treatment and the nature and seriousness
26 of the resident’s illness.

27 (2) The nature of the procedure to be used in the proposed
28 treatment, including the procedure’s probable frequency and
29 duration.

30 (3) The probable degree and duration, whether temporary or
31 permanent, of improvement or remission expected with or without
32 the proposed treatment.

33 (4) The nature, degree, duration, and probability of the side
34 effects and significant risks that are commonly known by the health
35 professions. Information on risks associated with psychotherapeutic
36 drugs shall include, but not be limited to, whether a proposed
37 medication is being prescribed for a purpose or medical condition
38 other than the purpose or medical condition for which the United
39 States Food and Drug Administration (FDA) has specifically
40 approved that medication. Information on risks of a proposed

1 medication shall also include, in writing, any current boxed
2 warning labels and accompanying detailed information regarding
3 contraindications, warnings, and precautions required by the FDA.

4 (5) The reasonable alternative treatments and risks, and why
5 the health professional is recommending a particular treatment.

6 (6) That the resident has the right to accept or refuse the
7 proposed treatment, and, if he or she consents, the right to revoke
8 his or her consent for any reason at any time.

9 (d) Before initiating the administration of psychotherapeutic
10 drugs, facility staff shall verify that the resident's health record
11 contains ~~documentation that the resident has given informed~~
12 ~~consent~~ *a notation by the attending or prescribing physician and*
13 *surgeon that the physician and surgeon has obtained the informed*
14 *consent of the resident* to the proposed treatment or procedure.
15 Facility staff shall also verify with the resident or the resident's
16 representative that the resident has ~~been fully informed about the~~
17 ~~proposed treatment or procedure and has consented,~~ *voluntarily*
18 *agreed to accept the proposed treatment or procedure after*
19 *receiving information from the attending physician and surgeon*
20 and shall document this verification in the resident's health record.
21 The facility shall also ensure that all decisions concerning the
22 withdrawal or withholding of life sustaining treatment are
23 documented in the resident's health record.

24 (e) Residents' rights policies and procedures established under
25 this section concerning consent, informed consent, and refusal of
26 treatments or procedures shall specify how the facility will verify
27 that the resident provided informed consent or refused treatment
28 or procedure pertaining to the administration of psychotherapeutic
29 drugs.

30 (f) This section shall not be construed to require obtaining
31 informed consent each time a treatment or procedure is
32 administered unless material circumstances or risks change.

33 (g) The State Department of Public Health shall inspect nursing
34 facilities for compliance with this section during the periodic
35 inspections required under Section 1422 and, as appropriate, during
36 complaint investigations required under Section 1420. This
37 inspection requirement shall not limit the department's authority
38 in other circumstances to cite for violations of this section or to
39 inspect for compliance with this section.

1 (h) A violation of the informed consent rights provided for in
2 this section may constitute a class “B,” “A,” or “AA” violation
3 pursuant to the standards established in Section 1424.

4 (i) *Nothing in this section shall impair or otherwise alter other*
5 *non-conflicting statutory or regulatory requirements, including,*
6 *but not limited to, requirements contained in paragraphs (e) to*
7 *(h), inclusive, of Section 72528 of Title 22 of the California Code*
8 *of Regulations or otherwise related requirements for informed*
9 *consent for the administration of psychotherapeutic drugs.*

10 ~~SEC. 6. Section 1599.3 of the Health and Safety Code is~~
11 ~~repealed.~~

12 ~~SEC. 7. Section 1599.3 is added to the Health and Safety Code,~~
13 ~~to read:~~

14 ~~1599.3. (a) If a resident lacks the capacity to understand his~~
15 ~~or her rights or the nature and consequences of a proposed~~
16 ~~treatment, the resident’s representative shall have the rights~~
17 ~~specified in this chapter to the extent the right may devolve to~~
18 ~~another, unless the representative’s authority is otherwise limited.~~
19 ~~The resident’s incapacity shall be determined by a court in~~
20 ~~accordance with state law or by the resident’s physician unless the~~
21 ~~physician’s determination is disputed by the resident or resident’s~~
22 ~~representative.~~

23 ~~(b) As used in this chapter, the term “resident’s representative”~~
24 ~~means a conservator, as authorized by Parts 3 and 4 (commencing~~
25 ~~with Section 1800) of Division 4 of the Probate Code, a person~~
26 ~~designated as attorney in fact in the resident’s valid durable power~~
27 ~~of attorney for health care, the resident’s next of kin, other~~
28 ~~appropriate legally recognized health care decisionmaker~~
29 ~~designated consistent with statutory and case law, a person~~
30 ~~appointed by a court authorizing treatment pursuant to Part 7~~
31 ~~(commencing with Section 3200) of Division 4 of the Probate~~
32 ~~Code, or, if the resident is a minor, a person lawfully authorized~~
33 ~~to represent the minor.~~

34 ~~SEC. 8.~~

35 ~~SEC. 6.~~ No reimbursement is required by this act pursuant to
36 Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 for a crime or infraction, within the meaning of Section 17556 of

- 1 the Government Code, or changes the definition of a crime within
- 2 the meaning of Section 6 of Article XIII B of the California
- 3 Constitution.

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